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09/734,801	12/12/2000	Roland Carlsson	EricPotter	5194

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CHUNDURU, SURYAPRABHA

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1637

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(6)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/734,801	CARLSSON ET AL.
	Examiner	Art Unit
	Suryaprabha Chunduru	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 September 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) Other: _____

DETAILED ACTION

1. Upon reconsideration and in view of the Applicants' arguments regarding the amendment and declaration (Paper Nos. 9 and 10), the previous office action is withdrawn herein. Further, finality of the previous office action is withdrawn in view of the telephonic interview and prosecution is reopened. Claims 1-6 are under consideration.
2. The Amendment (Paper No. 9) and Declaration (Paper No. 10) filed on September 19, 2002 have been entered and considered.

New Grounds of Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "adding primer sequences" in step c. There is insufficient antecedent basis for this limitation in the claim because the specification recites "no primers" in annealing step (reassembly of digested fragments). The instant claim recites adding primer sequences, lacks antecedent basis.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,159,690 in view of Kikuchi et al. (Gene, Vol. 243, pp. 133-137, 2000).

Although the conflicting claims 1-7 of the '690 patent are not identical, they are not patentably distinct from each other because claims 1-7 of the '690 patent are drawn to a method for generating a polynucleotide or population of sequences from parent polynucleotide sequences encoding one or more protein motifs, comprising the steps of (a) digesting the parent polynucleotide sequence which includes double-stranded or single-stranded parent polynucleotide sequences, with an exonuclease to generate a population of fragments; (b) contacting said fragments with template polynucleotide sequence under annealing conditions; (c) amplifying the fragments that anneal to the template in step (b) to generate at least one polynucleotide sequence encoding one or more protein motifs having altered characteristics as compared to the one or more protein motifs encoded by said parent polynucleotide. Further '690 patent discloses that (a) BAL3 as exonuclease; (b) parent polynucleotide sequences are subjected to mutagenesis(c) mutagenesis is error prone mutagenesis (error prone PCR). Claims 1-6 of the instant invention are drawn to the said method as disclosed by '690 patent. Although the '690 patent teach parent polynucleotide as being double or single stranded polynucleotide, the '690 patent did not specifically teach providing two separate populations of parent single stranded polynucleotide sequences constituting plus and minus strands.

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Kikuchi et al. teach a method for generating a polynucleotide sequence or a population of sequences from parent single stranded polynucleotide sequences encoding one or more protein motifs, wherein Kikuchi et al. discloses that the method comprises (a) providing single stranded polynucleotide sequences constituting plus and minus strands (complementary strands) of parent polynucleotide sequences wherein each of the complementary single strands (plus and minus) were derived from two separate parent single stranded polynucleotide containing plasmid vectors (SK-nahH and KS-xylE plasmids) and said first population (SK-nahH) generated from plus strands being separate from said second population (KS-xylE) generated from minus strands (see page 134, column 1, paragraph 2.3, page 135, Fig.1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of generating a polynucleotide sequence as claimed by Borrebaeck et al. ('690) with a method of DNA shuffling using single-stranded DNA as taught by Kikuchi et al. to achieve the claimed invention as a whole for the expected advantage of developing an improved and sensitivity method for generating a polynucleotide sequence with desired characteristics because Kikuchi et al. suggests that "the frequency of chimeric gene formation using single-stranded DNA would be much higher than when using the double-stranded DNA" (see page 136, column 1, paragraph 1). It would be obvious to a person of ordinary skill in the art at the time the invention was made, to combine the teachings of Borrebaeck et al. with the teachings of Kikuchi et al. in order to achieve an improved and sensitive method for generating a polynucleotide sequence with altered characteristics. Therefore, the instant claims are obvious over '690 in view of Kikuchi et al.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Kikuchi et al. (Gene, Vol. 243, pp. 133-137, 2000).

Kikuchi et al. teach a method for generating a polynucleotide sequence or a population of sequences from parent single stranded polynucleotide sequences encoding one or more protein motifs, wherein Kikuchi et al. discloses that the method comprises (a) providing single stranded polynucleotide sequences consisting of plus and minus strands (complementary strands) of parent polynucleotide sequences wherein each of the complementary single strands (plus and minus) were derived from two separate parent single stranded polynucleotide containing plasmid vectors (SK-nahH and KS-xylE plasmids) and said first population (SK-nahH) generated from plus strands being separate from said second population (KS-xylE) generated from minus strands (see page 134, column 1, paragraph 2.3, page 135, Fig.1); (b) digesting each single stranded polynucleotide sequences with an exonuclease to generate a first population of single stranded fragments (plus strands) and a second population of single strand fragments (minus strands) (see page 134, column 1, paragraph 2.3, page 135, Fig. 1, page 136, column 1, paragraph 1); (c) contacting said first and second population of single stranded fragments to anneal with each other (see page 134, paragraphs 2.2 - 2.3, page 135, Fig. 1); and (d) amplifying the annealed fragments to generate a polynucleotide sequence encoding one or more protein motifs having

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altered characteristics compared to said parent polynucleotides (see page (see page 134, paragraphs 2.2 - 2.3). Thus the disclosure of Kikuchi et al. meets the limitations in the instant claim 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (Gene, Vol. 243, pp. 133-137, 2000) in view of Borrebaeck et al. (6,159,690).

Borrebaeck et al. teach a method for generating a polynucleotide or population of sequences from parent polynucleotide sequences encoding one or more protein motifs, comprising the steps of (a) digesting the parent polynucleotide sequence which includes double-stranded or single-stranded parent polynucleotide sequences, with an exonuclease to generate a population of fragments (see column 2, lines 40-41); (b) contacting said fragments with template

polynucleotide sequence under annealing conditions (see column 2, lines 42-43); (c) amplifying the fragments that anneal to the template in step (b) to generate at least one polynucleotide sequence encoding one or more protein motifs having altered characteristics as compared to the one or more protein motifs encoded by said parent polynucleotide (see column 2, lines 44-48). Further Borrebaeck et al. discloses that (a) BAL3 as exonuclease (see column 3, lines 47-65); (b) parent polynucleotide sequences are subjected to mutagenesis is error prone PCR (see column 3, lines 16-46); annealing the exonuclease digested fragments in the presence of primer sequences (template sequences) (see column 3, lines 66-67, column 4, lines 1-6, column 14, lines 15-25). However, Borrebaeck et al. did not specifically teach providing single stranded polynucleotide sequences constituting plus and minus strand of parent polynucleotide sequences.

Kikuchi et al. teach a method for generating a polynucleotide sequence or a population of sequences from parent single stranded polynucleotide sequences encoding one or more protein motifs, wherein Kikuchi et al. discloses that the method comprises (a) providing single stranded polynucleotide sequences consisting of plus and minus strands (complementary strands) of parent polynucleotide sequences, wherein each of the complementary single strands (plus and minus) were derived from two separate parent single stranded polynucleotide containing plasmid vectors (SK-nahH and KS-xylE plasmids) (see page 134, column 1, paragraph 2.3); (b) digesting the single stranded polynucleotide sequences with an exonuclease to generate a first population of single stranded fragments (plus strands) and a population of second strands (minus strands) (see page 134, column 1, paragraph 2.3, page 135, Fig. 1, page 136, column 1, paragraph 1); (c) contacting said first and second population of single stranded fragments to anneal with each other (see page 134, paragraphs 2.2 - 2.3, page 135, Fig. 1); and (d) amplifying

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the annealed fragments to generate a polynucleotide sequence encoding one or more protein motifs having altered characteristics compared to said parent polynucleotides (see page (see page 134, paragraphs 2.2 - 2.3).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of generating a polynucleotide sequence encoding one or more protein motifs as taught by Borrebaeck et al. with the method for shuffling polynucleotide sequences using single stranded DNA as taught by Kikuchi et al. to achieve expected advantage of developing a sensitive method for generating a polynucleotide sequence(s) encoding one or more protein motifs having altered characteristics because Kikuchi et al. suggests that "the frequency of chimeric gene formation using single-stranded DNA would be much higher than when using the double-stranded DNA" (see page 136, column 1, paragraph 1). An ordinary practitioner would have been motivated to combine the method of Borrebaeck et al. with the method of Kikuchi et al. to enhance the sensitivity of the assay by incorporating the single stranded DNA shuffling in generating a chimeric polynucleotide sequence because this limitation would improve the method to obtain an altered polynucleotide sequence(s) with highly desirable characteristics.

Response to Arguments

6. Applicants' response to the office action (Paper No.9) is fully considered and deemed persuasive.
7. With respect to the rejection made in the previous office action under obviousness double patenting, Applicant's arguments and declaration (Paper No. 9) are considered but are moot in view of the new ground(s) of rejection. The rejection is moot in view of new art, which supports

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the obviousness double patenting in the presence of secondary reference. The rejection is rewritten as above.

8. With respect to the rejection made in the previous office action under 35 U.S.C. 102(e), Applicant's arguments (Paper No. 9) are considered but are moot in view of the new ground(s) of rejection. This rejection is moot in view of the new art rejection as discussed above which teach providing parent single stranded polynucleotide sequences constituting two separate plus and minus (complementary) single strands.

9. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicant's arguments (Paper No. 9) are considered but are moot in view of the new ground(s) of rejection as discussed above.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

SAC
Suryaprabha Chunduru

[Signature]
JEFFREY FREDMAN
PRIMARY EXAMINER